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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,300	02/13/2002	Yoram Reiter	02/23339	6257
7590	10/06/2006		EXAMINER	
Martin D.Moynihan PRTSI Inc P.O Box 16423 Arlington, VA 22215			VANDERVEGT, FRANCOIS P	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/073,300	REITER, YORAM	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 17 July 2006.  
 2a) This action is FINAL. 2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,2 and 4-17 is/are pending in the application.  
 4a) Of the above claim(s) 4-11 is/are withdrawn from consideration.  
 5) Claim(s) 13 is/are allowed.  
 6) Claim(s) 1,2,12 and 15-17 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed-Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## DETAILED ACTION

This application is a continuation-in-part of U.S. Application Serial Number 09/534,966.

Claim 3 has been canceled.

New claims 14-17 have been added.

Claims 1, 2 and 4-17 are currently pending.

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 17, 2006 has been entered.

### *Election/Restrictions*

2. **Claims 4-11 stand withdrawn** from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on June 8, 2004.

Accordingly, claims 1, 2, 12-17 are the subject of examination in the present Office Action.

3. **In view of Applicant's amendment filed July 17, 2006, no outstanding ground of rejection has been maintained.**

The following represents new grounds of rejection in response to Applicant's amendment filed July 17, 2006.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 1, 2, 12 and 14-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Claim 1 has been amended to recite "wherein all of said plurality of complexes are recognizable by one CTL clone" in an attempt to differentiate the claimed invention from the prior art. Applicant asserts that the amendment is supported by the instant specification at page 51, lines 19-23; page 52, lines 1-3; Figures 3a-3b; page 46, lines 16-23 and page 47, lines 1-13. However, no disclosure germane to the amendments to the claims can be found on any of the pages cited. Furthermore, pages 51 and 46 do not even have a line 23. In regard to Figures 3a-3b, there is no disclosure of a plurality of complexes that are all the same and no disclosure of binding to the same CTL. The figures merely depict a protein band of a single size.

New claims 14-17 each recite the term "monomeric complex(es)." Applicant asserts that the amendment is supported by the instant specification at page 46, line 19 and page 47, lines 1-13. However, no disclosure germane to the amendments to the claims can be found on any of the pages cited. Page 47 speaks only of scMHC-peptide complexes, not monomeric complexes.

Accordingly, given that the amendments to the claim are not supported by the specification as asserted by Applicant, the amendments constitute new matter and must be removed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14-17 are each ambiguous and unclear in the recitation of "monomeric complex(es)." The term is not disclosed or defined in the specification. A monomer is generally accepted in the art as being a singular polypeptide molecule, while a complex is a association of at least two polypeptide molecules. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant

intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mottez et al (J. Exp. Med. [1995] 181:493-502; U on form PTO-892, of record) in view of Lone et al (J. Immunotherapy [1998] 21(4):283-294; V on form PTO-892, of record).

Mottez teaches single chain constructs comprising a murine MHC class I heavy chain joined to  $\beta_2$ -microglobulin with a covalently bound antigenic peptide. Mottez teaches that linker, or spacer, sequences separate the segments (see entire document).

Mottez does not specifically teach human MHC class I heavy chain or  $\beta_2$ -microglobulin. However, in a continuation of the same work, Lone teaches that the same techniques were applied to human MHC class I heavy chain HLA-A2.1, which was joined via a 15-amino-acid linker to human  $\beta_2$ -microglobulin. Lone teaches that the single chain MHC class I construct folded properly and was functional (Abstract in particular). Lone teaches that the single chain MHC class I construct specifically bound HLA-A2 restricted peptides and induced peptide-specific cytotoxic T cells to proliferate and produce IL-2. given that Applicant's meaning of "monomeric complexes" is not defined in the specification and is therefore ambiguous, it is believed that the single chain MHC class I molecule of the combined references satisfies the metes and bounds of being a monomeric polypeptide complexed with an antigenic molecule.

It would have been *prima facie* obvious to a person having ordinary skill in the art at the time the invention was made to substitute human MHC class I as taught by Lone for the murine MHC class I bound to a specific peptide as taught by Mottez. One would have been motivated, with a reasonable expectation of success by the showing of Lone that the human MHC class I complex associated with peptide and activated T cells as well as the murine MHC class I complex did. One would have been further motivated by the teaching of Mottez that single chain MHC class I complexes can be useful for

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manipulating an immune response, particularly to an antigen that has low affinity for the MHC molecule (page 501, 2<sup>nd</sup> column in particular).

*Conclusion*

7. Claim 13 is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.  
Patent Examiner  
September 13, 2006

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